UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,170	07/30/2003	Sekhar Boddupalli	0118-CIP	7649

76656 7590 04/15/2010

Patent Docket Department
Armstrong Teasdale LLP
One Metropolitan Square
Suite 2600
St. Louis, MO 63102-2740

EXAMINER	
SCHLIENTZ, LEAH H	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
04/15/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USpatents@armstrongteasdale.com

Office Action Summary	Application No.	Applicant(s)	
	10/630,170	BODDUPALLI ET AL.	
	Examiner	Art Unit	
	Leah Schlientz	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-14* is/are rejected.

7)☒ Claim(s) *5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement of Receipt

Applicant's Response, filed 1/12/2010, in reply to the Office Action mailed 9/22/2009, is acknowledged and has been entered. Claims 1, 3-5 and 8-10 have been amended. Claims 11-14 are newly added. Claims 1-14 are pending and are examined herein on the merits for patentability.

Response to Arguments

Any rejection not reiterated herein has been withdrawn as being overcome by amendment.

Double Patenting

Claims 1-14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,667,330 in view of US 6,653,346, for reasons set forth in the previous Office Action.

Applicant argues on page 17 of the Response that a Terminal Disclaimer was filed to obviate the double patenting rejection.

However, the terminal disclaimer was disapproved. See entry in Public PAIR on 2/2/2010. See also MPEP 14.29.01. An attorney or agent, not of record, is not authorized to sign a terminal disclaimer in the capacity as an attorney or agent acting in

a representative capacity as provided by 37 CFR 1.34 (a). See 37 CFR 1.321(b) and/or (c). Accordingly, the double patenting rejections cannot be withdrawn at this time.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 and 6-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of contact dermatitis, acne, rosacea and psoriasis, does not reasonably provide enablement for additional claimed dermatologic conditions including skin irritation, regulating skin condition, regulating the signs of skin aging, age-related damage, or damage resulting from harmful radiation, environmental pollution, stress and fatigue. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,
2) the amount of direction or guidance provided,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the relative skill of those in the art,

7) the predictability of the art, and
8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth herein below.

The nature of the invention and the state of the prior art

The nature of the invention is a method for treatment of dermatological conditions selected from contact dermatitis, acne, rosacea and psoriasis, skin irritation, regulating skin condition, regulating the signs of skin aging, age-related damage, or damage resulting from harmful radiation, environmental pollution, stress and fatigue using the furanone derivatives of formula **I** or **III**. The state of the prior art is developed with regard to treating some of the above conditions with certain known therapeutic agents. For example, acne can be treated with benzoyl peroxide or salicylic acid.

The breadth of the claims, the relative skill of those in the art, and the predictability of the art

The claims are broad and include treatment of an assortment of discrete conditions with a very large number of potential furanone derivatives. There are millions of possible compounds encompassed by the claimed group of compounds having structural variables R^{1-4}, X and Y. There are a wide variety of dermatologic conditions encompassed by the instant claims which may have diverse etiology. Despite the advanced training of the ordinary practitioners in the pharmaceutical development and medical treatment arts, the arts are highly unpredictable. The state of the art is such that it is not possible to predict the activity of a compound, whether in vitro or in vivo, based

on the structure alone. Typically, for the development of a method of treating a disease, a certain pharmacological property of a compound, such as receptor binding or activation, or cytotoxicity, must be tested or verified in an in vitro model.

The amount of direction provided, the presence of working examples, and the quantity of experimentation necessary

In the instant case, in vitro Interleukin-1β Microglial Cell Assay, Mouse Ear Inflammatory Response to Topical Arachidonic Acid, Skin Protection Assay, and E-Selectin Cell Inflammation Assays were performed in Examples 41-45. The specification indicates that the claimed compounds are useful in treating diseases characterized by oxidative stress and/or inflammation. While conditions to include contact dermatitis, acne, rosacea and psoriasis have be shown to be associated with an inflammatory process, and therefore a reasonable correlation between the in vitro utility and in vivo activity may be expected, it would require a great deal of experimentation to determine the efficacy of the broad range of compounds claimed for other conditions such as skin irritation, regulating skin condition, regulating the signs of skin aging, age-related damage, or damage resulting from harmful radiation, environmental pollution, stress and fatigue. For example, with respect to "regulating skin condition," it is unclear how such treatment would be evaluated and what type of "regulation" is to occur, and how such regulation is reasonably associated with inflammation. For example, what tangible effect does regulation of skin condition involve? With respect to "regulating signs of aging," it is also unclear the extent to which the compounds are considered to be effective. All humans are prone to skin

aging over time, and since no "fountain of youth" has been discovered to date, it is unclear what measurable degree of skin aging is to be "regulated." For example, wrinkles, sagging, moles, etc. may be associated with skin aging, irradiation, pollution, stress, fatigue but do not necessarily require inflammation as a pathway for development. Additional claimed conditions also do not necessarily require inflammation, for example, skin irritation can be a result of dry skin, allergic reaction, bacterial infection, etc. MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 999, F.2d 1557, 1562, 27 USPQ2d 1510, 1513(Fed Cir. 1993." The instantly claimed methods of treating skin irritation, regulating skin condition, regulating the signs of skin aging, age-related damage, or damage resulting from harmful radiation, environmental pollution, stress and fatigue with compounds of the formula in claim 1 that are shown to have *in vitro* anti-inflammatory activity are not enabled.

Claim Objections

Claim 5 is objected to as being dependent upon a rejected base claim, but is free of the prior art of record.

Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is (571)272-9928. The examiner can normally be reached on Monday-Tuesday and Thursday-Friday 9 AM-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

LHS